

United States Patent and Trademark Office

Commissioner for Patents United States Patent and Trademark Office Alexandria, VA 22313-1

MAR 2 7 2008

Stephen Baxter Oblon, Spivak, McClelland, Maier & Neustadt, PC 1940 Duke Street Alexandria VA 22314

In Re: Patent Term Extension Application for U.S. Patent No. 6,107,458

Dear Mr. Baxter:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 6,107,458 for a period of 1,265 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner

for Patent Examination Policy

cc: Office of Regulatory Policy Food and Drug Administration

10903 New Hampshire Ave., Bldg. 51, Rm. 6222

Silver Spring, MD 20993-0002

RE: MYCAMINE®

FDA Docket No.: 2006E-0023

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 6,107,458

(45) ISSUED : August 22, 2000

(75) INVENTOR : Hidenor Ohki, et al.

(73) PATENT OWNER : Astellas Pharma Inc.

(95) PRODUCT : MYCAMINE® (micafungin sodium)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 6,107,458 based upon the regulatory review of the product MYCAMINE® (micafungin sodium-NDA No. 21-506) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,265 days

from September 29, 2015, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this <u>26th day</u> of <u>March</u> 2008.

Jon W/Dudas

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office